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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,807	09/18/2003	David White	MPI99-130P1RCN1M	2119

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,807	WHITE, DAVID	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/20/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-9, 13-16, and 39-41, drawn to methods of diagnosing and/or detecting predisposition for a bone-related disorder requiring determination of a nucleotide sequence, classified in class 536, subclass 25.32, for example.

II. Claims 1-6, drawn to methods of diagnosing a bone-related disorder requiring detection of differences in gene expression levels, classified in class 435, subclass 6, for example.

III. Claims 1-6, drawn to methods of diagnosing a bone-related disorder requiring determination of the protein content of a patient's tissue, classified in class 435, subclass 7.1, for example.

IV. Claims 1-6, 10-12, 17-18, 21, and 23-24, drawn to methods of diagnosing and/or alleviating a bone-related disorder requiring administering to a patient an MRR protein binding agent or antagonist, classified in class 424, subclass 130.1, for example.

V. Claims 17-19 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an MRR protein, classified in class 514, subclass 2, for example.

VI. Claims 17-20 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering a vector, classified in class 514, subclass 44 and class 435, subclass 320.1, for example.

VII. Claims 17-18 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an agonist of MRR protein activity, classified in class 514, subclass 2, for example.

VIII. Claims 17-18 and 23-24, drawn to methods of alleviating a bone-related disorder requiring administering an enhancer of MRR expression, classified in class 514, subclass 2, for example.

IX. Claims 17-18 and 22-24, drawn to methods of alleviating a bone-related disorder requiring administering an inhibitor of mrr expression, classified in class 514, subclass 44 and class 536, subclass 24.5, for example.

X. Claims 25-31 and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determining MRR protein activity, classified in class 435, subclass 7.4, for example.

XI. Claims 25-27, 29-33, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring comparing mrr gene expression, classified in class 435, subclass 6, for example.

XII. Claims 25-27, 34, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determining a bone phenotype, classified in class 435, subclass 7.24, for example.

XIII. Claims 25-27, 35, and 37-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring administering the compound to a transgenic animal, classified in class 800, subclass 3, for example.

XIV. Claims 25-28 and 36-38, drawn to methods of determining whether a test compound alleviates a bone related disorder requiring determination of protein activity in an artificial membrane, classified in class 435, subclass 7.2, for example.

The inventions are distinct, each from the other because of the following reasons: Inventions I-XIV are patentably distinct methods. First, Inventions I-IV and V-IX, I-IV and X-XIV, and V-IX and XIV differ from each other in having different objectives: Inventions I-IV have the objective of diagnosing a bone-related disorder, Inventions V-IX have the objective of treatment, and Inventions X-XIV have the objective of determining the usefulness of a test compound. Furthermore, each of Inventions I-XIV requires the use of different combinations of reagents and the practice of differing method steps. Invention I requires the use of, e.g., sequencing reagents in a step of determining a nucleotide sequence. Invention II requires the use of, e.g., oligonucleotide probes in a step of determining gene expression levels. Invention III requires the use of, e.g., a labeled antibody in a step of determining the protein content of a tissue. Invention IV requires the use of, e.g., a binding reagent in a pharmaceutical carrier in a step of administering a binding reagent to a patient. Invention V requires the use of a portion of

an MRR protein in a step of administering a polypeptide to a patient. Invention VI requires the use of an expression vector in a step of administering a vector to a patient. Invention VII requires the use of an agonist in a step of administering an agonist to a patient. Invention VIII requires the use of mrr expression enhancer in a step of administering an enhancer to a patient. Invention IX requires the use of, e.g., an antisense oligonucleotide in a step of administering an mrr expression inhibitor. Invention X requires the use a cell comprising biologically active MRR in a step of comparing MRR activity. Invention XI requires a step of a test compound and, e.g., an oligonucleotide probe in a step of determining mrr gene expression. Invention XII requires the use of, e.g., a microscope in a step of determining a bone phenotype. Invention XIII requires the use of a non-human transgenic animal in a step of administering a compound to said animal. Invention XIV requires the use of artificial membranes in a step of determining activity in said membrane. Accordingly, the methods of Inventions I-XIV are patentably distinct from each other.

It is pointed out that applicants have presented several claims in improper Markush format (see Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 328). Method claims encompassing multiple distinct methods requiring the use of different reagents in distinct method steps are improperly joined, as the different methods encompassed by the claims differ to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, restriction has been set forth for each of the various groups, irrespective of the improper format of the claims. Claims 1-6, 17-19, 23-27, 29-31, and

37-38 have been included in multiple groups, and if elected, will be examined only as they read upon the invention of the elected group.

Upon election, applicants are further required to amend the claims to set forth the elected inventive group; otherwise the claims under examination will be rejected as being in improper Markush format.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph. D.
Patent Examiner
Art Unit 1649
August 8, 2005

JOSEPH MURPHY
PATENT EXAMINER